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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,533	11/14/2003	Pierre Druilhe	02356.0086	5870

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EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/712,533

Applicant(s)

DRUILHE ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8-40 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) 1,12-40,43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8,9 and 42 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/05, 6/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment filed July 25, 2006 is acknowledged and has been entered. Claims 2, 3, 6, 7 and 41 have been canceled. Claims 4, 5, 9 and 34 have been amended. Claims 1, 4, 5, 8-40 and 42-44 are now pending in the present application.

2. Applicant's election without traverse of Group II (claims 4, 5, 8-11 and 42, SEQ ID NO: 3) in the reply filed on July 25, 2006 is acknowledged.

The Office acknowledges Applicants' request for rejoinder of process claims that include all limitation of elected product claim when it is established that a product claim is allowable (see MPEP 821.04)

3. Claims 1, 12-40, 43 and 44 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 25, 2006.

4. The use of trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

5. The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see p. 43. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

6. Acknowledgment is made of applicant's claim for foreign priority based on an applications filed in CANADA 2345206 on 5/16/01 and CANADA 2346968 on 5/23/01. It is noted, however, that applicant has not filed a certified copy of an English translation of each of the applications as required by 35 U.S.C. 119(b).

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The claim is vague and indefinite in the recitation of "at least one polypeptide". Claim 8 depends claim 4. Claim 4 recites only one polypeptide. Claim 8 lacks antecedent basis for the recitation of "at least one".

8. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the claimed invention. The specification, at p. 4, lines 8-11, sets recombinant E. coli cells deposited at CNCM on May 23, 2001 with the accession numbers I-2671 and I-2604. It appears that these cells are necessary to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, a deposit of the above plasmid may satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See 37 C.F.R. 1.802.

It is noted that the plasmid has been deposited. However, the certificate of deposit has not been provided nor have the statements of assurance been made, see below. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository (with address) and that the following criteria have been met:

- (a) during the tendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- © the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless,–

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Hoffman et al discloses an isolated or purified polypeptide of Plasmodium falciparum, comprising a peptide sequence corresponding to SEQ ID NO: 3 (SEQ ID NO: 29 p. 82 and 83, Table 2 see sequence search results printout).

ID AAB18205 standard; protein; 1712 AA. AC AAB18205; DT 07-NOV-2000 (first entry) DE Plasmodium falciparum chromosome 2 related protein SEQ ID NO:62. KW Plasmodium falciparum; chromosome 2; human malaria parasite; vaccine; KW antimalarial; malaria; protozoacide; infection; insecticide. OS Plasmodium falciparum. PN WO200025728-A2. PD 11-MAY-2000. PF 05-NOV-1999; 99WO-US026796. PR 05-NOV-1998; 98US-0107131P. PA (HOFF/) HOFFMAN S. PA (CARU/) CARUCCI D. PA (GARD/) GARDNER M. PA (VENT/) VENTER J C. PI Hoffman S, Carucci D, Gardner M, Venter JC; DR WPI; 2000-365347/31. PT Proteins encoded by chromosome 2 of the human malarial parasite, PT Plasmodium falciparum, useful as antimalarial vaccines and in the PT diagnosis of P.falciparum infection. PS Disclosure; Page 141-146; 577pp; English. The present invention describes proteins and their fragments (I) encoded by chromosome 2 of the human malarial parasite, Plasmodium falciparum. Also described are: (1) nucleotide sequences (II) encoding (I); and (2) vaccines against P. falciparum infection comprising (I) or (II). (I) and (II) are useful for the development of vaccines against P. falciparum infection. (I) and polyclonal antisera or a monoclonal antibody raised to immunogens comprising the sequences of (I), are useful in the detection of infection with P. falciparum. Furthermore, (I) (especially when they are rifins or secreted or membrane proteins) can aid the identification of drugs to treat or prevent P. falciparum infection, or they can be used to identify drug resistance in P. falciparum. Sequencing of the Plasmodium chromosome 2 and the subsequent identification of proteins encoded by it will help to expand our understanding of parasite biology, a process hampered by the complexity of the parasitic lifecycle, and provide new targets for vaccine and drug development. Parasite resistance to drugs and mosquito resistance to insecticides have led to a resurgence of malaria in many parts of the world, and there is a pressing need for vaccines and new drugs. AAA70078 to AAA70287 and AAB18144 to AAB18352 represent nucleotide and protein sequences given in the present invention, but which are not specifically mentioned within the specification.

Db · 517 SSKKKNKILTNNHHSSDNQNCHSSDNQNCHSSDNQNCHSSDNQNCHSSDNQNC D 570

Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide with the polypeptide of the prior art reference, the burden is upon applicants to show a distinction between the material structural

and functional characteristics of the claimed polypeptide and the polypeptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. Claims 4, 5, 8, 9 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardner et al (Science 1998, 282:1126-1132).

See sequence search result:

RESULT 1 A71622 hypothetical protein PFB0155c - malaria parasite (Plasmodium falciparum) C;Species: Plasmodium falciparum C;Date: 13-Nov-1998 #sequence_revision 13-Nov-1998 #text_change 21-Jul-2000 C;Accession: A71622
R;Gardner, M.J.; Tettelin, H.; Carucci, D.J.; Cummings, L.M.; Aravind, L.; Koonin, E.V.; Shallom, S.; Mason, T.; Yu, K.; Fujii, C.; Pederson, J.; Shen, K.; Jing, J.; Aston, C.; Lai, Z.; Schwartz, D.C.; Perte, M.; Salzberg, S.; Zhou, L.; Sutton, G.G.; Clayton, R.; White, O.; Smith, H.O.; Fraser, C.M.; Adams, M.D.; Venter, J.C.; Hoffman, S.L. Science 282, 1126-1132, 1998 A;Title: Chromosome 2 sequence of the human malaria parasite Plasmodium falciparum. A;Reference number: A71600; MUID:99021743; PMID:9804551 A;Accession: A71622
A;Status: preliminary; nucleic acid sequence not shown; translation not shown
A;Molecule type: DNA
A;Residues: 1-507 <GAR>
A;Cross-references: UNIPARC:UPI000017B602; GB:AE001376; GB:AE001362; NID:g3845108; PIDN:AAC71821.1; PID:g3845110; TIGR:PFB0155c
A;Experimental source: clone 3D7
C;Genetics:
A;Gene: PFB0155c
Query Match 81.8%; Score 284; DB 2; Length 507;
Best Local Similarity 91.7%; Pred. No. 2.8e-18;
Matches 55; Conservative 1; Mismatches 4; Indels 0; Gaps 0;
Qy 3 HMHDYTYDDRIYNNDKEKNVIKSDNKNVIKSDNKNDYKKCNKNVIKSDNKNVIKSDNKNV 62
:|||||
Db 80 NMHDYTYDDRIYNNDKEKNVIKSDNKNVIKSDNKNVIKSDNKNVIKSDNKNVIKSDNKNV 139

Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide with the polypeptide of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptide and the polypeptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



N. M. Minnifield
NITA MINNIFIELD
PRIMARY EXAMINER

AU 1645
4-1-07